IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

RETRACTABLE TECHNOLOGIES, INC. and THOMAS J. SHAW,	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. 2:07-CV-250 (DF)**
BECTON, DICKINSON & COMPANY,	§	
Defendant.	§	

O R D E R

This case is set on the Court's October 2009 trial docket. Before the Court is Defendant Becton, Dickinson and Company's ("BD's") Motion to Exclude Expert Testimony of William A. Hyman. Dkt. No. 180. Also before the Court are Plaintiffs' ("RTI's") response and BD's reply. Dkt. Nos. 198 and 213. The parties have also submitted Dr. Hyman's entire April 29, 2009 report to the Court. Having considered the briefing and all relevant papers and pleadings, the Court finds that BD's motion should be GRANTED IN PART and DENIED IN PART.

I. LEGAL PRINCIPLES

Federal Rule of Evidence ("Rule") 702 requires that any expert be qualified to testify by "knowledge, skill, experience, training, or education":

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if
>
> (1) the testimony is based upon sufficient facts or data,
>
> (2) the testimony is the product of reliable principles and methods, and

(3) the witness has applied the principles and methods reliably to the facts of the case.

Any such testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." *Id.* When faced with a proffer of expert testimony, it is the trial judge's responsibility to determine, at the outset, whether the expert is proposing to testify to expert knowledge and whether such testimony will assist the trier of fact to understand or determine a fact in issue. *Id.*; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993). In this regard, the trial judge acts as a gatekeeper by requiring a valid connection to the pertinent inquiry and assessing "whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline." *Daubert*, 509 U.S. at 592; *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999).

Rule 401 states: "'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Rule 402 states: "All relevant evidence is admissible, except as otherwise provided . . . . Evidence which is not relevant is not admissible." Rule 403 states: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."

II. DISCUSSION

BD moves pursuant to Rules104(a), 401, 402, 403, and 702, as well as the principles of *Daubert*, to exclude the testimony of William A. Hyman, a professor of biomedical engineering,

as irrelevant and based only "on a cursory examination of a handful of devices in counsel's office and a review of BD documents selected by plaintiffs' counsel." Dkt. No. 174 at 1-2. BD also argues that Dr. Hyman "strays far beyond the scope of human factors engineering, Mr. Hyman's stated area of expertise, and discusses BD's market power and alleged copying of the VanishPoint [even though RTI] has put forth no evidence to qualify Mr. Hyman as an expert on business or marketing." *Id.* at 2. BD further argues that Dr. Hyman has "[s]elect[ed] anecdotes cherry-picked from documents produced in this case." *Id.* at 4. BD submits that the Court should strike Dr. Hyman's entire report or, alternatively, the Court should strike: paragraphs 74-106 and opinion numbers 3 and 5 of paragraph 115 as unreliable product evaluations; paragraphs 4, 70, 72, 90, 97, 101-104, 109-114 and opinion numbers 2, 6, and 7 of paragraph 115 as unreliable business or marketing opinions; and paragraphs 3, 72, 98, and 104 as unsubstantiated opinions regarding purported copying of the patented design. *Id.* at 5, 6, and 7.

RTI replies that Dr. Hyman "is an acknowledged expert in human factors, that is, the interface between the design features of a device and the users of that device," and has opined on several topics:

> (1) the ways in which "safety" syringes cause injuries; (2) the long-felt need for an effective safety syringe design; (3) factors that a successful design must address in order to minimize to the maxim[um] extent possible exposure to bloodborne pathogens as a result of accidental needle stick injuries and splatter; and (4) how five products measure up to those standards.

Dkt. No. 198 at 1. RTI submits that these topics are "directly relevant to both validity and damages, assisting the jury to understand and assess":

> (1) the long-felt need to address the dangers of syringes; (2) the variety and failure of design efforts to adequately address that problem; (3) why from a human factors perspective previous designs failed and why they are not "acceptable

> substitutes;" and thus (4) the inventiveness, unique need for and value of the technology at issue in this patent litigation.

Id. at 2. As to business and marketing matters, "[t]here is no Rule 702 requirement that Prof. Hyman prove himself to be an expert in business or marketing in order to review what BD's own officers, designers, and salespeople have to say about the BD safety syringes." *Id.* at 10-11. RTI also argues that BD's market dominance is relevant to a human factors analysis because "many nurses and other frontline end-users will have used only or mostly BD syringes." *Id.* at 11. RTI also argues that Dr. Hyman does not present an opinion on infringement, contrary to BD's representations. *Id.* at 13-14. Finally, RTI argues that Dr. Hyman should be permitted to testify regarding a device known as the NMT Safety Syringe, which was admitted to infringe RTI's asserted patents in another case in this District. *Id.* at 14-15 (citing Stipulation and Consent Judgment, Civil Action No. 4:02-cv-34 (E.D. Tex.)).

BD replies:

> RTI's post hoc re-characterization of Mr. Hyman's opinions is a calculated effort to present prejudicial and highly inflammatory testimony before the jury that defendant Becton, Dickinson and Company ("BD") is a monopolist, that its products are unsafe, and that it is intentionally deceiving the public in marketing literature and advertisements. RTI's antitrust, unfair competition, and false advertising allegations are not before this jury, are irrelevant, and should be excluded under Federal Rules of Evidence 401-403.

Dkt. No. 213 at 1-2. BD also argues that Dr. Hyman's opinions on ergonomic design are irrelevant to long-felt need, failure of others, commercial success, non-infringing substitutes, or the value of the purported inventions. *Id.* at 2-4.

The Court finds that Dr. Hyman is qualified as an expert in mechanical engineering and biomedical engineering, based at least on his advanced degrees and his experience in those fields. *See* Dkt. No. 198 at 4; *see also* 4/29/2009 Hyman Report, Dkt. No. 180, Ex. A at ¶¶ 5-7 and

Appx. 1 (pp. 4 and 41-51 of report).

As to relevance, RTI should not be required to present its case in a vacuum, and Dr. Hyman presents useful background discussion on practical considerations of needlestick risks and safety syringe design. *See, e.g.,* 4/29/2009 Hyman Report, Dkt. No. 180, Ex. A at ¶¶ 11-69 (pp. 7-23 of report). Dr. Hyman's report includes opinions that are reasonably related to issues such as long-felt need for the purported invention and availability of non-infringing substitutes, even if Dr. Hyman does not give opinions on ultimate issues of law or fact such as validity or damages. For example, Dr. Hyman's human factors analyses of BD's "Safety-Lok," "SafetyGlide," and "Eclipse" syringes are apparently probative regarding obviousness factors such as purported long-felt needs and failure of others to fulfill those needs. *See id.* at ¶¶ 74-97 (pp. 25-30 of report).

As to reliability, Dr. Hyman cites various studies, treatises, and BD's own documents. Dr. Hyman's product evaluations are evidently based on his training and experience in engineering and human factors. *See* 4/29/2009 Hyman Report, Dkt. No. 180, Ex. A at ¶¶ 74-114 (pp. 25-38 of report). Also, Dr. Hyman evaluated several syringes during the course of forming his opinions. *See* 7/15/2009 Hyman dep., Dkt. No. 198, Ex. 2 at 32:9-34:25 and 38:1-41:22. Further, although BD criticizes some of Dr. Hyman's opinions as unreliably addressing business or marketing issues, these opinions are at least facially supported by documentary evidence and Dr. Hyman's expertise. *See, e.g.,* 4/29/2009 Hyman Report, Dkt. No. 180, Ex. A at ¶¶ 109-114 (pp. 36-38 of report). Finally, Dr. Hyman notes that infringement of RTI's asserted patents is alleged, but Dr. Hyman does not directly opine on infringement. *See id.* at ¶¶ 3, 72, 98, and 104 (pp. 2, 24, 30, and 33). On balance, BD's arguments regarding the factual bases and methodologies underlying Dr. Hyman's opinions are better directed to the weight of Dr. Hyman's

testimony than to its admissibility. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Dr. Hyman also presents opinions regarding the amount of BD's market power or efforts to maintain market power. *See, e.g.,* 4/29/2009 Hyman Report, Dkt. No. 180, Ex. A at ¶¶ 70-73, 90, 97, 104, and 115 (pp. 24, 28, 30, 33, and 39 of report). Such opinions should be STRICKEN pursuant to Rule 403 because any probative value is likely substantially outweighed by the danger of unfair prejudice.[1] *See* Fed. R. Evid. 403; *see also* Order regarding BD's Motion to Exclude Expert Testimony of Walter Bratic, entered contemporaneously with this Order.

Further, Dr. Hyman opines on a human factors analysis of BD's accused products, the "Integra" syringes. *See* 4/29/2009 Hyman Report, Dkt. No. 180, Ex. A at ¶¶ 98-105 and Table 1 (pp. 30-35 of report). The central inquiry in a patent infringement case is generally a comparison of the asserted claims to the accused products. As to Dr. Hyman's opinions that the "Integra" is a "bad copy" of RTI's product, such opinions go to RTI's lost profits theory that BD has purportedly "poisoned the market" for retractable syringes. *See id.* at ¶ 104 ("Another effect of the Integra being a poorly performing product is that it has adversely affected the general concept of retractables among those who have experienced the Integra. This, along with market access issues, has damaged the ability for others, such as RTI, to demonstrate and market a device that actually works."); *see also* Order regarding BD's Motion to Exclude Expert Testimony of Walter Bratic, entered contemporaneously with this Order. First, any probative value of Dr. Hyman's human factors analysis of the accused products is substantially outweighed by the likelihood of

[1] The paragraphs identified in the preceding sentences are given as examples of where such opinions can be found, and the Court does not necessarily strike those paragraphs in their entirety.

unfair prejudice and jury confusion. *See* Fed. R. Evid. 403. Second, as discussed in the Court's contemporaneous Order regarding the opinions of Mr. Bratic, fairness does not permit RTI to present a previously-resolved antitrust case instead of the patent infringement case that is actually at bar. Dr. Hyman's human factors analysis of the accused products (the "Integra") is therefore STRICKEN.

Finally, Dr. Hyman opines as follows regarding the NMT Safety Syringe:

> One measure of the value of the RTI technology is that, before being forced to abandon the technology, NMT raised millions of dollars in the stock market based on their copy of it. NMT tried and apparently failed to develop a second-generation safety syringe before it was bought and delisted from the London stock exchange.

See 4/29/2009 Hyman Report, Dkt. No. 180, Ex. A at ¶ 111. Although RTI submits that this opinion is relevant to the absence of *non-infringing* alternatives (because NMT admitted that its product infringed RTI's patents), Dr. Hyman did not frame his opinion about the NMT Safety Syringe in this fashion. Instead, Dr. Hyman's opines that optimism about the NMT Safety Syringe bears on the value of RTI's patents, but any possible relevance in this regard is substantially outweighed by the danger of unfair prejudice and jury confusion. *See id.*; Fed. R. Evid. 403. Also, any probative value of this opinion is further minimized because the stipulation relied upon by Dr. Hyman was obtained through litigation. *See* Civil Action No. 4:02-cv-34 (E.D. Tex.), Dkt. No. 148. Dr. Hyman's opinions regarding the NMT Safety Syringe should therefore be STRICKEN.

III. CONCLUSION

For at least the foregoing reasons, BD's Motion to Exclude Expert Testimony of William A. Hyman (Dkt. No. 180) is hereby **GRANTED IN PART** and **DENIED IN PART**. Dr. Hyman's opinions regarding the amount of BD's market power or efforts to maintain market

power are hereby **STRICKEN**. Also, Dr. Hyman's opinions regarding a human factors analysis of the accused products are hereby **STRICKEN**. Further, Dr. Hyman's opinions regarding the NMT Safety Syringe are hereby **STRICKEN**.

To the extent that Dr. Hyman's opinions are not stricken herein, BD's motion is expressly **DENIED IN PART**.

IT IS SO ORDERED.

SIGNED this 2nd day of October, 2009.

DAVID FOLSOM
UNITED STATES DISTRICT JUDGE